FEB - 6 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: May 14, 2008

1. Company and Correspondent making the submission:

Name - Shenzhen Creative Industry Co., Ltd.
Address - 2/F, Block 3, Nanyou Tian'an Industry Town, Shenzhen, China
Telephone - +86-755-2643 4955
Fax - +86-755-2643 5433
Contact - Jianbin Liu
Email - liujianbin@creative-sz.com

2. Device :

Trade/proprietary name: Fetal Doppler, Model PC-860
Common Name : Fetal Doppler
Classification Name : Monitor, Ultrasonic, Fetal

Predicate Device: Edan Instruments, Inc., Ultrasonic Pocket Doppler Model: Sonotrax 510(K) number: K040480

3. Classifications Names & Citations :

21CFR 884.2660, KNG, Fetal Doppler, Class II

4. Description

4.1 General

This Doppler tests the fetal heart rate through non-invasive ultrasonic Doppler Effect. As is known, ultrasonic wave propagating at a given frequency will be reflected when encountering an obstacle. If it is still an obstacle, the back wave will share the same frequency with the transmitted wave. Once the obstacle moves, the frequency of the back wave will be changed. The higher rate the object moves at, the bigger frequency change will take place. This is the so-called Doppler Effect. With the apparatus, the ultrasonic probe is placed on the abdomen of the pregnant woman. The ultrasonic probe can perceive the fetal heartbeat. When the transmitted wave encounters the fetal heart, the back wave will develop offset frequency. With the offset frequency, the fetal heart rate and frequency can be worked out.

4.2 Directions

As discussed in the General description, the Shenzhen Creative Industry Co., Ltd Fetal Doppler, model PC-860 is relatively simple to use. The Doppler is placed on the abdomen of the patient by first feeling out the fetal contour with hand to find the approximate position of fetal heart. Generally, fetal heart is at a location 113 of the lower abdomen (below the navel) during short pregnant weeks, and along with the pregnant weeks increasing, it moves upwards and lean to right or lean to left. To scan the abdomen, the user must first daub the acoustics surface of Doppler probe uniformly with the appropriate ultrasonic gel, and then put the probe on pregnant woman's abdomen (a location near fetal heart). It is important to ensure that probe contacts surface completely.

5. Indication for use :

The device is an ultrasonic fetal heart beat detector, which can detect the Fetal Heart Rate. The built in speaker of the device allows for listening of the fetal heartbeat.

6. Comparison with predicate device :
   Shenzhen Creative Industry Co., Ltd., believes that the Fetal Doppler, Model PC-860 is substantially equivalent to the Edan Instruments, Inc., Ultrasonic Pocket Doppler, Model: Sonotrax, 510(K) number: K040480

7. Safety and Performance Data :
   Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1. Clinical testing was used to validate the effectiveness and accuracy of the device. Specific testing relating to Ultrasound equipment was use to verify performance to recognized standards. All test results were satisfactory.

8. Conclusions:
   In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Shenzhen Creative Industry, Inc., Ltd concludes that Fetal Doppler, Model PC-860 is safe and effective and substantially equivalent to predicate devices as described herein.

9. Shenzhen Creative Industry Co., Ltd. will update and include in a summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Shenzhen Creative Industry Co., Ltd.
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street, N.W.
BUFFALO MN 55313

Re: K082055
Trade/Device Name: PC-860 Fetal Doppler
Regulation Number: 21 CFR §884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: January 22, 2009
Received: January 23, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082055

Device Name: PC-860 Fetal Doppler

Indications For Use:

The device is an ultrasonic fetal heart beat detector, which can detect the Fetal Heart Rate. The built in speaker of the device allows for listening of the fetal heartbeat.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082055